



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

Friday, October 07, 2016

MEMORANDUM

Subject: EPA File Symbol/Reg. No.: 3573-RNN

Product Name: Markie
DP Barcode: D434423
Decision No.: 518443
Action Code: A530
PC Code: 069149

From: Ian Blackwell, M.S.
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Through: OPP Similarity Clinic

Jenny Tao, Senior Toxicologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

To: Eric Miederhoff, PM 31/ Karen Leavy
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: The Procter & Gamble Company

<u>PC Code</u>	<u>Active Ingredient(s):</u>	<u>% by wt.</u>
069149	Didecyl dimethyl ammonium chloride	0.33
	<u>Other Ingredient(s):</u>	<u>99.67</u>
	Total:	100.00

OPP Similarity Clinic

- I BACKGROUND: The Procter & Gamble Company asks for a Similarity Clinic comparison between their new product 3573-RNN (Markie) and 3573-99 (Vesta). Both of these products contain didecyl dimethyl ammonium chloride as the active ingredient. Vesta was found to be Substantially Similar to Felix II 5X (an unregistered product).
- II DECISION: The Similarity Clinic finds 3573-RNN to be Substantially Similar to 3573-99. This is based upon a comparison of the 6/10/2016 basic CSF to the 7/10/2013 basic CSF of 3573-99. The acute toxicity profile of 3573-99 was cited from "Felix II 5X", an unregistered product.
- III TOXICITY PROFILE: CTT cited the following acute toxicity profile from 3573-99 and is using it to support 3573-RNN, "Markie".

Study	MRID Number	Toxicity Category	Study Status
Acute Oral Toxicity	49081707	IV	Cited
Acute Dermal Toxicity	49081708	IV	Cited
Acute Inhalation Toxicity	49081709	III	Cited
Primary Eye Irritation	49081710	III	Cited
Primary Skin Irritation	49081711	III	Cited
Dermal Sensitization	49081712	Nonsensitizer	Cited

IV LABELING:

PRODUCT NAME: "Markie"

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

"Harmful if inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Avoid breathing spray mist. Remove and wash contaminated clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco."

First Aid:

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

If inhaled:

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Friday, October 07, 2016

Note to File:

The two CSFs compared by CTT (mentioned above) are identical in formulation. Thus, if Vesta (3573-99) is Substantially Similar to Felix, Markie (3573-RNN) will be also. The acute toxicity of Felix II 5X was addressed in the 11/12/13 review of 3573-99 (D413018).

Ian Blackwell